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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,766	01/19/2005	Toshimitsu Baba	2005-0022A	2679

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EXAMINER	
HA, JULIE	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,766	BABA ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary amendment filed on January 19, 2005 is acknowledged. Claims 1-7 are pending in this application. Claims 1-7 are examined on the merits in this office action.

Objection-Minor Informalities

1. The title is objected to because the title is too long. The title is limited to 5-7 words maximum. A new title is required that is clearly indicative of the invention to which the claims are directed.

Rejection-35 U.S.C. 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Soybean 7S protein is a natural phenomenon and is not directed to a practical application of such judicial exception (e.g., because the claim does not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result). The 7S protein occurs naturally in soybeans. Howard et al (US Patent # 4368151) teach that the 2S, 7S, 11S and 15S protein are the most commonly reported soy protein fractions. Soybeans as a Food Source reports the 2S protein typically comprises approximately 22%, the 7S approximately 37%, the 11S approximately 31% and the 15S approximately 11% of the total weight of the protein composition (see column 1, lines 7-19).

Rejection-35 U.S.C. 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Howard et al (US Patent # 4368151).

6. The instant claims are drawn to an agent containing soybean 7S protein as an active ingredient, containing 2.5% or less of polar lipids in a solid content, and 1.2% or less of phytic acid in a solid content. The claims are further drawn to foodstuffs containing the agent.

7. Howard et al teach a method of fractionating an isolating by precipitation of 11S and 7S isolates of soybean protein (see abstract). Further, the reference teaches a means for improving the amount of recoverable proteins from vegetable materials...the isolation process does not alter the native character of the protein isolates, and permits recovery of an isolated fraction free from salt contamination. Furthermore, the isolated proteins were determined upon the basis of their sodium dodecyl sulfate polyacrylamide gel electrophoresis profile (see column 7, lines 25-38). Since the isolated proteins by themselves can be considered "an agent", this reads on claims 1-4 and 6-7. The reference further teaches that the defatted leguminous seed materials, especially defatted soybean material, are particularly suitable as a crude 11S and 7S mixture

source material. Exemplary defatted soybean material sources for the 7S and 11S mixture includes soybean meal, soy flour, soy grits, soy protein concentrates, soy isolates, mixtures thereof and the like (see column 3, lines 53-59). This reads on claim 5, since natural soybean meal would contain an active ingredient of 7S protein. The reference further teaches that upon completion of the 11S and 7S extraction, the water-insolubles are advantageously separated from the soluble extracts. This permits the subsequent isolation and recovery of protein precipitates substantially free from cellulosic contamination (see column 4, lines 51-56). Since the proteins are "purified", this reads on 2.5% or less of polar lipids and 1.2% or less of phytic acid of claims 3-4 and 6-7. Furthermore, any food, any composition, and agent containing the 7S protein as an active ingredient would necessarily lower the body fat percentage of anyone who takes the 7S protein. Therefore, the prior art reads on all of the claims, 1-7.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-2, 4-5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kohno et al (US Patent # 7186425).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a

showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

9. The instant claims are drawn to an agent lowering body fat percentage or an inhibitor of body fat percentage increase containing soybean 7S protein as an active ingredient. The claims are further drawn to an agent comprising 1.2% or less of phytic acid in a solid content of soybean 7S protein.

10. Kohno et al teach a neutral fat reducing composition which reduces a blood neutral fat safely and efficiently, and whose active ingredient is a soybean protein containing 50% or more of a 7S globulin fractionated from a soybean protein and 0.2% or less of phytate based on the protein (see abstract). As evidence by Truestar Health Encyclopedia, Phytate is also known as Inositol Hexaphosphate (IP-6) and phytic acid (see Truestar enclosed or http://www.truestarhealth.com/Notes/2868007.html). Thus, this reads on claims 1, 2, 4 and 7. The reference teaches that a blood neutral fat reducing effect of a soybean protein has already been established based on a body fat-reducing effect of the soybean protein, and to be an inhibitory effect on the activity of a fatty acid synthetase in a liver. Additionally, each of a whole soybean globulin, a 7S globulin and a 11S globulin was examined for its effect on fats in blood and a liver, and was reported generally to be more excellent in terms of an ability of reducing blood cholesterol or neutral fat when compared with casein which is an animal protein (see column 1, lines 16-26). This also reads on claims 1, 2 and 4. Furthermore, the reference teaches that an objective is to obtain a fraction having a blood neutral fat reducing

ability from the soybean proteins and to treat this fraction for enhancing its ability, whereby providing it as a food or a pharmaceutical (see column 2, lines 6-9). This reads on claims 1 and 5. Furthermore, the reference teaches that a fraction (7S globulin) or a soybean protein employed as an active ingredient is a safe edible material, the amount of which to be incorporated into a composition or to be ingested is not limited particularly, and may be ingested as it is or may be incorporated into a food product for a dietary therapy (see column 4, lines 19-24). This further reads on claims 1 and 5.

Obviousness Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of U.S. Patent No. 7186425.

Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the composition of U.S. Patent # 7186425 claims, one would necessarily achieve the same agent for lowering body fat percentage or an inhibitor of body fat percentage containing soybean 7S protein as an active ingredient as the instant application. The instant claims are drawn to an agent lowering body fat percentage or an inhibitor of body fat percentage containing soybean 7S protein as an active ingredient, containing 2.5% or less of polar lipids and 1.2% or less of phytic acid.

13. However, U. S. Patent No. 7186425 a composition for reducing the blood level of neutral fats, comprising as an active ingredient a 7S globulin-rich phytate-reduced soy protein, whose phytate content is 0.2% or less based on the soybean protein, comprising 1% or less of chloroform: methanol (2:1)-extractable oil portion based on the soybean protein (see claims 1-3 and 5). When one administers the composition of the U.S. Patent, one would necessarily achieve the same effect of lowering body fat percentage or inhibiting body fat percentage.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Julie Ha
Patent Examiner
AU 1654

3/27/07
ANISH GUPTA
PRIMARY EXAMINER